



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,575	06/26/2003	David Edgren	ARC3234R1	4693
27777 7590 04/23/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/606,575	Applicant(s) EDGREN ET AL.	
	Examiner Hasan S. Ahmed	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-35,38-44 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-35,38-44 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- Receipt is acknowledged of applicants' amended claims and remarks, which were filed on 10 January 2007.
- The 35 USC 102(b) rejection is withdrawn in light of the amendment.
- The obviousness-type double patenting rejection is withdrawn in light of the remarks.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-35, 38-44, and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the release of a therapeutic agent as a solution or suspension to the environment (see claim 25). Based on the instant disclosure, it is the examiner's position that Applicants do not describe this invention in such a manner that would enable one of ordinary skill in the art to practice this invention without undue burden. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to

Art Unit: 1615

make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

The breadth of claims: Instant claim 25 is directed to a controlled release oral dosage form wherein the therapeutic agent is released as a solution or suspension to the environment. It is the examiner's position that this claim is not supported by the instant specification.

The nature of the invention: The instant invention is directed to a dosage form comprising a core (consisting of a low solubility therapeutic agent, a structural polymer, and a solubilizing surfactant) surrounded by a semi-permeable membrane, and an exit orifice, wherein the therapeutic agent is released as a solution or suspension to the environment.

The amount of direction provided by the inventor: The instant application provides no evidence that the therapeutic agent being released is actually in solution or suspension form; no data are provided to that effect.

The presence or absence of working examples: There are no examples in the instant specification which indicate that the therapeutic agent being released is actually in solution or suspension form.

The quantity of experimentation: A burdensome amount of research would be required by one of ordinary skill in the art to arrive at the release of a therapeutic agent in solution or suspension, as claimed. In order to utilize the invention as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 25-35, 38-44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatt, *et. al.* (U.S. Patent No. 6,368,626) in view of Chen, *et. al.* (U.S. 2003/0077297).

Bhatt, *et. al.* disclose a controlled release oral dosage form (see col. 3, lines 10-31). The disclosed dosage form is comprised of:

- the once-a-day administration of claim 25 (see col. 7, line 8);
- the core comprising: (a) a low solubility therapeutic agent (e.g. dioxin – see col. 7, line 63); (b) a structural polymer (see col. 19, line 25); and (c) the soluble surfactant of instant claim 25 (see col. 13, line 6);
- the semi-permeable membrane surrounding the core of instant claim 25 (see col. 3, line 13);
- the solution (viscous fluid) of instant claim 25 (see col. 5, line 31);
- the exit orifice of instant claim 25 (see col. 3, line 12);
- the extended release of instant claim 25 (see col. 7, line 6);
- the zero order release rate of instant claim 26 (see figure 3);
- the ascending release rate of instant claim 27 (see figure 7);

- the high dose of low solubility therapeutic agents of instant claim 28 (see col. 6, line 55);
- the method for enhancing the bioavailability of a therapeutic agent by administration said dosage form to a subject of instant claim 29 (see col. 3, line 40);
- the release of a high dose of therapeutic agent of instant claim 30 (see col. 6, line 55);
- the 20%-90% content of therapeutic agent of instant claim 31 (see col. 6, line 57);
- the 200,000 MW polyethylene oxide of instant claim 41; and
- the poloxamers of instant claim 42 (see, col. 20, line 53).

Bhatt, *et. al.* explain that their dosage form comprising a core (consisting of a low solubility therapeutic agent, a structural polymer, and a solubilizing surfactant) surrounded by a semi-permeable membrane, and an exit orifice is beneficial in bringing about "...the substantially complete release of a drug from the dosage form, particularly from dosage forms that may require high drug loading in order to have the desired pharmacological effect." See col. 6, lines 46-49.

The Bhatt, *et. al.* reference differs from the instant application in that it does not teach the use of the active agent "topiramate" or the solubilizing surfactant "poloxamer 407".

Art Unit: 1615

Chen, *et. al.* teach a controlled release oral dosage form (see paragraph 0040). The disclosed dosage form may comprise topiramate (see paragraph 0068) and poloxamer 407 (see table 15).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add topiramate and poloxamer 407 to a controlled release formulation, as taught by Bhatt, *et. al.* in view of Chen, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to make a dosage form comprising a core (consisting of a low solubility therapeutic agent, a structural polymer, and a solubilizing surfactant) surrounded by a semi-permeable membrane, and an exit orifice because of the beneficial effects substantially complete release of a drug from the dosage form, particularly from dosage forms that may require high drug loading in order to have the desired pharmacological effect, as explained by Bhatt, *et. al.*

*

2. Claims 32-35, 38-40, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatt, *et. al.* (U.S. Patent No. 6,368,626)

Bhatt, *et. al.* disclose a controlled release oral dosage form (see above).

While Bhatt, *et. al.* do not explicitly teach all the instant claimed percentages and dosage levels, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages and dosages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in percentage and dosage level will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such percentage and dosage level is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage and dosage level ranges.

* * * * *

Response to Arguments

Applicant's arguments filed 10 January 2007 have been fully considered but they are not persuasive.

Applicants argue that the instant application is distinguished from the Bhatt, et. al. reference because instant claim 25 has been amended to recite the limitation "solution or suspension," while, "the dosage form taught by Bhatt, et. al. is designed to release the active ingredient from the dosage form in a 'dry or substantially dry state.'"
See remarks, page 7, last paragraph.

Art Unit: 1615

Examiner respectfully submits that the limitation "solution" is very broad, and encompasses a wide range of physical forms – from gas to solid. Generally, a solution is defined as:

A uniformly dispersed mixture at the molecular or ionic level, of one or more substances (the solute) in one or more other substances (the solvent). These two parts of a solution are called phases. Common types are: (a) liquid-liquid: alcohol-water; (b) solid-liquid: salt-water; and (c) solid-solid: carbon-iron. See Hawley's Condensed Chemical Dictionary, 14th Edition.

No definition is provided for "solution" in the instant specification; i.e. no limitations are provided for viscosity properties, etc.

The drug layer disclosed by Bhatt, et al. consists of a uniformly dispersed mixture of active agent and carrier (see col. 13, lines 20-44; example 1). Thus, affording the term "solution" its broadest reasonable interpretation, examiner respectfully submits that the therapeutic agent disclosed by Bhatt, *et al.* is a solution.

* * * * *

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1615

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

★

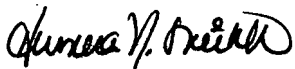
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


HUMERA N SHEIKH
PRIMARY EXAMINER